Supreme Court, U.S.
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JOSEPH F. SPANIOL, JR.
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No. 86-513

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

v.

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether Petitioner is merely attempting to argue once again the facts previously heard and adjudicated without alleging a significant issue for review or showing any departure from the course of accepted judicial proceedings?

2. Whether the United States Court of Appeals, Eleventh Circuit, created a new oral testimony standard or conflict among the circuits?

3. Whether Petitioner's complaints about credibility determinations and deference to governmental committee findings are applicable to the facts of this case?

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The Respondents respectfully request this Court deny the Petition for Writ of Certiorari seeking review of the Eleventh Circuit's Opinion in this case.

STATEMENT OF THE CASE INCLUDING THE NATURE OF THE PROCEEDINGS AND THE DISPOSITION BELOW

This diversity product liability action alleges Petitioner's product, Ortho-Gynol Contraceptive Jelly, after failing to prevent conception caused birth defects in the child thus conceived.

Katie Wells, the daughter of Mary Maihafer and Gary Wells, was born on July 1, 1981 with several birth defects, including the complete lack of a left arm with only partial development of her left clavicle and shoulder, abnormal formation of her right hand, a cleft lip and nostril deformity.

On September 2, 1982, Katie Wells, by Mary Maihafer and Gary S. Wells, and Mary Maihafer, Individually, instituted their action against Petitioner Ortho Pharmaceutical Corp. (Ortho). The Complaint stated a cause of action for negligence, strict product liability, intentional tort and breach of warranty. In essence, Respondents alleged that: (1) Ortho-Gynol contraceptive jelly, a spermicide, caused Katie Wells' birth defects; (2) Ortho's product contained no warning that it could cause birth defects; (3) Ortho's product was defective for lack of adequate warning; (4) Ortho negligently failed to warn; and (5) Ortho's defective product and negligent failure to warn proximately caused the birth defects. The Complaint sought damages for Katie Wells' pain and suffering, medical expenses and disability, as well as Mary Maihafer's mental distress and lost wages. Respondents also sought punitive damages.

The parties subsequently agreed to waive a jury and the case was tried to the District Court (Honorable Marvin H. Shoob) from January 8 through January 22, 1985. Both sides presented substantial expert witness testimony. Their

opinions often were diametrically opposed relative to the major elements of the case. In an effort to resolve these direct conflicts in the experts' opinions, the trial judge "regularly examined daily transcripts of much of the expert testimony and spent an entire weekend reviewing the studies introduced." *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 266 (N.D. Ga. 1985); A-33.[1]

The trial court found that Respondents had proven to a reasonable degree of medical certainty the birth defects of Katie Wells' left arm and shoulder and right hand were proximately caused by Ortho's product. Finding Respondents also met the other prima facie elements of their negligence and product liability theories, the trial court awarded damages exceeding $5.1 million.

The trial court, some six months later, entered its Order detailing extensive Findings of Fact and Conclusions of Law. *Wells*, 615 F. Supp. 262; A-29-194. The Order included a denial of Ortho's Motion To Reopen. Final Judgment was entered on August 1, 1985.

The Petitioner filed its Notice of Appeal in the United States Court of Appeals for the Eleventh Circuit on August 29, 1985. On appeal, Ortho raised the questions presented here by strenuously urging the court to focus its attention on a number of "studies". Ortho propounded then and now that their "studies" should singularly control the outcome in this product liability action. The Eleventh Circuit Panel, after thorough evaluation and analysis of the same issues presented here, issued a detailed opinion finding these claims to be without merit and affirming the District

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1. Citations to "A" herein refer to Petitioner's Appendix filed with its present Petition; "T" refers to the trial transcript; "OP" refers to Ortho's Petition for Certiorari; and "OAB" refers to Ortho's Appellate Brief.

Court's Judgment in favor of Respondents.[2] *Wells*, 788 F.2d 741.

The Eleventh Circuit denied Ortho's Petition for Rehearing and suggestion for rehearing *en banc* on June 27, 1986.[3] *Wells*, 795 F.2d 89; A-203-205.

REASONS FOR DENYING THE WRIT

I.

PETITIONER ATTEMPTS TO ARGUE ONCE AGAIN THE FACTS PREVIOUSLY HEARD AND ADJUDICATED WITHOUT ALLEGING A SIGNIFICANT ISSUE FOR REVIEW OR SHOWING ANY DEPARTURE FROM THE COURSE OF ACCEPTED JUDICIAL PROCEEDINGS.

Petitioner seeks to retry the merits of its case. The first twelve (12) pages of Petitioner's Brief argue facts previously presented to the trial court. Actual trial evidence in the form of several studies is presented by Petitioner in its "Lodging" with this Court. This "Lodging" of evidence is a continuance of Petitioner's attempt to argue that which has been decided by a competent trier of fact. A Writ of Certiorari is "not [to be used] to review evidence and discuss specific facts." *United States v. Johnston*, 268 U.S. 220, 227 (1925).

Petitioner's blatant statement in the first sentence of its Statement Of The Case designed to pique the attention of its reader that "with the exception of Plaintiffs' experts in this case, no scientist has ever publicly expressed an

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2. The Appellate Court reduced the total amount of the Award but such reduction is not part of Petitioner's present Argument.

3. Respondents' Petition for Rehearing on the damage issue was denied on the same date. A-206-208.

opinion that spermicides cause birth defects," overlooks its *own* "Lodging" with this Court at Page 24 of a *JAMA* article which makes just such a statement. This *Journal of the American Medical Association* article published April 3, 1981, is authored by several scientists (Hershel Jick, M.D.; Alexander M. Walker, M.D., MPH; Kenneth J. Rothman, Dr.PH; et al.) who did not testify as experts for the Plaintiffs. *They publicly expressed* at page 26:

COMMENT

> The present data show a positive association between vaginal spermicide use and certain congenital disorders, namely, limb reduction deformities, neoplasms, chromosomal abnormalities, and hypospadias.

To continue its fact-bound argument before this Court in itself falls outside the guidelines of Supreme Court Rule 17.1 on a Petition for Writ of Certiorari. To then misstate those facts to this Supreme Court categorizes not only the merit of its petition but Petitioner's credibility as well.[4]

Ortho has had its day in court. After a procedurally perfect trial, extensive findings of fact and conclusions of law, an unsuccessful appeal of the same issues presented here and denial of motions for reconsideration and rehearing *en banc*, Petitioner steadfastly persists in clogging this Court's docket with argument of issues that do not warrant this Court's attention. Since there is ample evidence to support the trial court's conclusions, Ortho is not entitled to now remarshal those facts favorable to its argument in hopes that this Court will sit as another trier of fact.

The United States Supreme Court's review of issues on Writ of Certiorari is not a matter of right, but of judicial

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4. The failure of a petitioner to present with accuracy. . . the points requiring consideration will be a sufficient reason for denying his petition. Sup. Ct. R. 21.5.

discretion and will be granted only when there are special and important reasons. *Rice v. Sioux City Cemetery*, 349 U.S. 70,73 (1954), Sup. Ct. R. 17.1. The questions presented must involve principles, the settlement of which have importance to the public as distinguished from the parties. *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387,393 (1923). A loss on the merits is not a special and important reason.

II.

THE UNITED STATES COURT OF APPEALS, ELEVENTH CIRCUIT, NEITHER CREATED A NEW ORAL TESTIMONY STANDARD OR CONFLICT AMONG THE CIRCUITS.

A. The Eleventh Circuit's Review Of The Entire Record Complies With Fed. R. Civ. P. 52(a) and *Anderson v. City of Bessemer City*, 470 U.S. 564, 105 S. Ct. 1504 (1985).

Petitioner alleges the Eleventh Circuit, "narrowed the scope of its review to the *oral testimony* of Plaintiffs' experts. . ." without evaluating its plausibility in light of scientific evidence. OP-14. Petitioner made the same argument on appeal to the Eleventh Circuit alleging the District Court narrowed the scope of its decision to the oral testimony of Plaintiffs' experts without evaluating its plausibility in light of the scientific evidence. OAB-34-72.

Notwithstanding Petitioner's own argument at the Circuit level and the Circuit's express recognition of Fed. R. Civ. P. 52(a)[5] and *Anderson*,[6] (A-6), Petitioner would have this Court believe the Circuit Court never reviewed the rec-

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5. Fed. R. Civ. P. 52(a) provides in pertinent part, "Findings of fact, whether based on oral or documentary evidence, shall

(cont'd on next page)

ord in this case but relied solely on Plaintiffs' oral expert testimony thereby creating a new standard.

This oral testimony focus is belied by the opening portion of the Eleventh Circuit opinion wherein it was noted the panel reviewed "*the extensive factual record*" to affirm with respect to Ortho's liability. *Wells*, 788 F.2d at 742; A-2.

In next determining the accuracy of trial court findings of CAUSATION, the Eleventh Circuit stated, "*After reviewing the record* we reject Ortho's arguments and conclude that the district court's finding of causation is not clearly erroneous." *Id.* at 744; A-9 (emphasis supplied). The Eleventh Circuit further stated, "*We note.* . .[not the district court noted] that plaintiffs presented well qualified experts. . .[and] [P]laintiffs presented several epidemiological studies that indicated an association between spermicide use and deleterious effects on the fetus." *Id.*; A-9-10 (emphasis supplied).

In determining the accuracy of the trial court's findings on FAILURE TO WARN the Eleventh Circuit stated, "*We*

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not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses."

6. This Court in *Anderson* stated:

> "In applying the clearly erroneous standard to the findings of a district court sitting without a jury, appellate courts must *constantly* have in mind that their function is not to decide factual issues *de novo*." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123, 89 S. Ct. 1562, 1576, 23 L.Ed.2d 129 (1969). If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous. *Id.* at 1511-12.

conclude that this finding is not clearly erroneous in light of the *evidence present in the record.*" *Id.* at 746; A-18 (emphasis supplied). The Eleventh Circuit, in recognizing several studies were available to Ortho prior to 1980, stated, "The district court found, *and we agree* that these studies were available to Ortho [prior to 1980]." *Id.* (emphasis supplied). The Eleventh Circuit necessarily reviewed the record in order to agree with the District Court findings.

Oral testimony became the focus of the Eleventh Circuit when addressing the District Court's reference to experts testifying about scientific studies and the credibility determinations necessarily made when that oral testimony was in direct conflict. After reviewing the methodology applied by the District Court the Circuit Court concluded, "We are satisfied that the district court's extensive credibility determinations are not clearly erroneous." *Id.* at 745 n. 8; A-14 at n. 8.

Excerpts of the Eleventh Circuit's opinion outlined above show the Panel did review the entire record including the District Court findings and conclusions prior to its unanimous decision of no clear error. Such a review is in direct conformity with Fed. R. Civ. P. 52(a) and decisions of this Court.[7]

B. Cases Cited By Petitioner Establish That No Conflict Exists Between The Circuits.

Petitioner has cited three cases for the proposition the methodology contained therein somehow conflicts with the

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7. *Anderson, supra* and cases cited therein.

methodology applied by the Eleventh Circuit. Such is not true.

1. *Wisconsin v. Weinberger, 745 F.2d 412 (7th Cir. 1984)*; *OP-20-21*

Petitioner misstates this case in an attempt to suggest the *scientific studies* in evidence were dispositive on the issue of whether the Navy acted arbitrarily and capriciously in deciding not to perform an amended enviromental impact statement.

The Seventh Circuit fully recognized its duty was not to dissect the scientific evidence as Petitioner herein suggests, but to consider the evidence as a whole:

> Of course, it is not necessary for our purposes to consider in detail the merits of the scientific allegations and the alleged shortcomings of each piece of information and reach our own scientific decision about the project. *That is not our function.*
> *Id.* at 421 (emphasis supplied).

After considering the evidence as a whole the Seventh Circuit in *Weinberger* deemed it *insufficient* to carry the burden of proof to show the Navy acted arbitrarily and capriciously. The Eleventh Circuit in this case after considering the evidence as a whole deemed it *sufficient* to carry Plaintiffs' burden of proof.

2. *Moultrie v. Martin, 690 F.2d 1078 (4th Cir. 1982); OP-21.*

Petitioner's reliance on *Moultrie* is equally misplaced. *Moultrie* involved the appeal of a trial court's denial of a Writ of Habeas Corpus. The trial court had determined that statistical evidence presented to support a claim of dis-

crimination was insufficient and thus Petitioner failed to make out a prima facie case. The Appellate Court agreed and affirmed.

In the instant action however, the trial court determined that evidence (including statistical) presented to support proof of Causation and Failure To Warn was sufficient and Respondent *did* make out a prima facie case. The Appellate Court, as in *Moultrie*, agreed and affirmed.

3. *Lima v United States, 708 F.2d 502 (10th Cir. 1983)*; *OP-21.*

Lima is procedurally analogous to the instant action as it was a Rule 52 (a) bench trial on the issue of causation in a swine flu case. The trial court upon proper objection, ruled inadmissable the testimony of one of Plaintiff's expert witnesses and found Plaintiff did not carry his burden of proof. The Tenth Circuit, applying the clearly erroneous standard, affirmed the trial court findings.

In the present case there was no objection to Plaintiffs' expert testimony. The trial court concluded that Plaintiffs carried their burden of proof, and as in *Lima*, the Circuit Court applying the clearly erroneous standard, affirmed the trial court findings.

In summary, Petitioner has failed to show the Eleventh Circuit opinion conflicts with this Court's opinions or with the opinions of its sister circuits (*see also, Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984)). The Eleventh Circuit relied on *this Court's* controlling decisions and correctly applied the clearly erroneous standard to the facts before it. No conflict of decision exists in other circuits.

III.

PETITIONER'S COMPLAINTS ABOUT CREDIBILITY DETERMINATIONS AND DEFERENCE TO GOVERNMENTAL COMMITTEE FINDINGS ARE INAPPLICABLE TO THE FACTS OF THIS CASE.

Citing the Tort Policy Working Group's comments on Insurance Availability and Affordability (OP-23), Petitioner embraces two recommendations made by such group. The courts should first become more aggressive in determining the credibility of scientific and medical evidence and opinions; second, greater deference must be given to governmental agencies.

As to the courts being more aggressive in determining credibility, petitioner overlooks the fact this case is a prime example of such effort. As previously noted, the trial judge in addition to hearing courtroom testimony, routinely reviewed daily transcripts of much of the expert testimony and spent an entire weekend reviewing the scientific studies. As recognized by the Eleventh Circuit, the trial court made extensive credibility determinations applying appropriate methodology.[8]

Petitioner's argument for more aggressive credibility determination calls for all scientific cases being heard by a trial judge to avoid jury sympathy and reliance on a particular expert because the jury likes the witness. A Federal

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8. In assessing credibility the court looked at each expert's background, training, experience, and familiarity with the circumstances of this particular case. The court examined each expert's testimony in terms of its rationality and internal consistency in relation to all the evidence presented. The court also looked at each expert's demeanor and tone and searched for motives, biases, and interests that might have influenced opinion. *Wells*, 788 F.2d at 745 n.8; A-14 at n. 8.

District Court Judge sitting without a jury having tried this case, Petitioner's complaint appears to be the adverse result of the very process it embraces.

The second recommendation of the Tort Policy Working Group urged by Petitioner is greater deference to governmental committee recommendations. (OP-24 n.2).

Petitioner has selected the *wrong case* to espouse the theory of deference to governmental agencies. The two reports introduced by Petitioner upon the trial of this case and considered by the District Court and Eleventh Circuit, when subjected to *discovery* and *cross examination* showed gross incompetence and corporate influence by Ortho.

As to the first agency advisory panel relied on by Petitioner (The O.T.C. Advisory Committee) (OP-5):

> Discovery and Cross Examination were able to establish *at least* the following:
>
> Dr. Armond Welsh, a committee member, testified for Ortho as to information gathered by the committee prior to its 1980 recommendation. The report was *tainted with incompetence* when Dr. Welsh testified on cross examination, that during the 1970's there was a *rumor* of a report at NIH [Oechsli Study (1976)] which linked spermicides with birth defects. Though it was his job to do so, Dr. Welsh never got the report and never confirmed the *rumor*, yet the committee proceeded to denote the product "safe and effective". T 1103.

As to the second agency advisory panel relied on by Petitioner (FMHDAC) (OP-5):

This advisory subcommittee of the FDA, met on December 15, 1983 and discussed whether or not they should

recommend the addition of a pregnancy warning to spermicides.

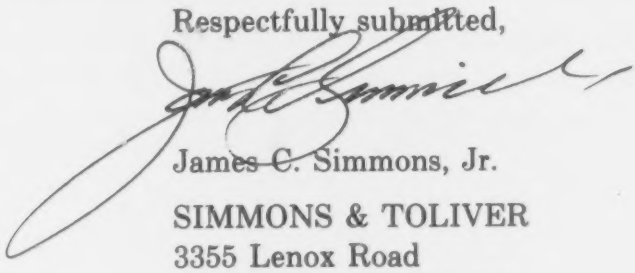
> Discovery and Cross Examination were able to establish *at least* the following:
>
> The committee consisted of seven members who heard testimony from sixteen individuals, at least six of whom were either employed by, or paid travel expenses and consulting fees by Ortho Pharmaceutical Corporation. T-1540. Dr. Brent, Ortho's key expert at trial, was one of the seven voting committee members though he did not *recuse* himself or *disclose* to his fellow judges his prior contact with Ortho and his involvement with this lawsuit for six (6) months prior to the hearing. T-1678.

Petitioner urges blind acceptance of governmental agency (Advisory Subcommittee) conclusions as controlling in a state tort action. The incompetence of the O.T.C. Advisory Committee's literature search and the influence Ortho had on both the FMHDAC Panel of Judges and those presenting testimony were important items considered by the District Court in determining how much weight to give their conclusions. Deference to these committee findings could well have shielded their failings from discovery. This very case is an example of how the adversary process with full right of cross examination adds assurance the Judgment will reflect the *truth and right of the case.*

CONCLUSION

For the reasons set forth above, Ortho's Petition for a Writ of Certiorari should be denied.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing RESPONDENTS' BRIEF IN OPPOSITION upon Petitioner by depositing four copies of same in the United States mail, first class, postage prepaid to:

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